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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,712	03/31/2000	DONALD H. RUBIN	01123.0004	8103

7590 05/08/2002

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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	14

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/509,712	RUBIN ET AL.	
	Examiner	Art Unit	
	Shanon A. Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 25-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group IV, corresponding to claims 24 and 30 in Paper No. 7 and applicant's election without traverse of species of SEQ ID NO: 75 is also acknowledged in Paper No. 13. Claims 1-23 and 25-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7 and 13.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because it cannot be determined how the compound, the cellular gene comprising SEQ ID NO: 75, and the gene product that is necessary for viral replication, but not for cell survival are related to one another. Evaluation of the effectiveness of the compound is measured by detecting the level of activity or decrease of the gene product. If the addition of the compound only affects the gene product, what is the relationship between the gene product and SEQ ID NO: 75 and the compound? The claims also state that the cell contains

a cellular gene that comprises SEQ ID NO: 75. Is SEQ ID NO: 75 native to the genetic makeup of the cell or is the sequence transfected? It cannot be determined if SEQ ID NO: 75 is an unisolated natural product or not. Claim 30, step d) states that the level of viral infection is "associated" with the cellular gene, but it is unclear what the association is or how it is made. The metes and bounds of what would be considered a homolog of SEQ ID NO: 75 also cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a nucleic acid homolog of SEQ ID NO: 75. The specification states on page 10 that a nucleic acid homolog is at least 50% homologous to SEQ ID NO: 75, which is 833 nucleotides in length. 50% variation of 833 nucleotides is approximately 416 nucleotides. Therefore, the scope of the homolog encompasses sequences that are structurally and functionally unrelated to SEQ ID NO: 75. It is unclear how a nucleic acid sequence that shares only 50% homology with SEQ ID NO: 75 can be functionally similar to SEQ ID NO: 75 or encodes a product with the required function of reproduction of a virus in a cell, but not necessary for the survival of a cell. The specification does not teach how to structurally modify SEQ ID NO: 75 or how the skilled artisan would readily identify a sequence with the required

functions. The claims read on nucleic acid sequences with no defined structure, and the specification does not reasonably convey possession of these undefined sequences.

Claims 24 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of screening a compound for the effectiveness in treating or preventing any viral infection by administering a compound to a cell containing a cellular gene comprising SEQ ID NO: 75 or a homolog thereof and a gene product necessary for the production of a virus, contacting the cell with a virus, and correlating the amount of viral infection with the gene product expression to determine the compound's effectiveness in treating or preventing any viral infection. As discussed above, it cannot be determined what the relationship is between the compound, the cellular gene, and the gene product. It also cannot be determined how the *in vitro* association between the gene product and the compound are associated with *in vivo* amelioration and/or prevention of any viral infection. The specification teaches on page 35, lines 31-33, that SEQ ID NO: 75 has homology to *H. sapiens* zinc finger transcription factor mRNA. The specification does not teach whether this homology is based on the percentage of sequence identity or evolutionary relationship. A sequence search reveals that SEQ ID NO: 75 is a rat U3 gene trap derived nucleic acid, see the Geneseq sequence alignment provided of SEQ ID NO: 75 with Dubois et al. (WO 99/19481-A2, 7/24/1999, ID NO: AAX57445). SEQ ID NO: 75 also has 53.8% sequence similarity to SEQ ID NO: 1 encoding 2A5-3 lambda CHO sequence from a Chinese hamster of Morris et al. (US 6,027,915), see the

sequence alignment provided. The prior art does not teach that viral infections are directly linked to association with zinc finger transcription factors, rat U3 gene trap nucleic acids, or nucleic acid sequences from Chinese hamsters. There is no teaching in the specification that correlates every viral infection to these genes. The specification does not teach identifying antiviral compounds and does not teach how every virus would be susceptible to the compound based on the amount of gene product expressed. The specification also does not teach a method of correlating *in vitro* assay data with *in vivo* results and the skilled artisan would doubt that data obtained from an *in vitro* assay would be immediately applicable *in vivo* or that the results predict the effect on any virus, known and unknown. There are no working examples that demonstrate the association between a compound, a cellular gene, and a gene product that is indicative of an antiviral effect. The skilled artisan would not be able to identify a structural and functional homolog of SEQ ID NO: 75 or identify an effective *in vivo* antiviral compound with the instant method.

Therefore, due to the scope of the claims drawn to identifying compounds that are antiviral against any known and unknown viruses, the lack of teaching in the prior art drawn to viral infection and association with zinc finger transcription factors, rat U3 gene trap nucleic acids, or nucleic acid sequences from Chinese hamsters, the lack of teaching and working examples in the specification identifying *in vivo* antiviral compounds with the instant method, the lack of teaching of how the compound, the gene product, and the cellular genes are associated, the lack of teaching provided for how the skilled artisan would be able to structurally identify a homolog of SEQ ID NO: 75, it is determined that an undue amount of experimentation would be required of the skilled artisan to make and use the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
April 26, 2002

JAMES HOUSEL 5/6/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600